

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES
INTERNATIONAL, INC. and ARIUS
TWO, INC.,

Plaintiffs,

v.

ALVOGEN PB RESEARCH &
DEVELOPMENT LLC, ALVOGEN
MALTA OPERATIONS LTD.,
ALVOGEN PINE BROOK LLC,
ALVOGEN, INC., and ALVOGEN
GROUP, INC.,

Defendants.

C.A. No. 18-1395 (CFC)

PLAINTIFFS' MOTION TO STRIKE

I. INTRODUCTION

Defendants' opening and reply post-trial briefs improperly rely on documents that were not admitted into evidence and defenses that were never raised in the more than two and a half years of litigation or even during trial. Accordingly, to ensure compliance with proper procedure and that Plaintiffs' positions are preserved for any appeal, Plaintiffs move to strike these new documents and legal defenses. Lead and Delaware counsel for the parties met and conferred via phone pursuant to D. Del. LR 7.1.1, and the parties could not resolve the issues.

II. ARGUMENT

In their post-trial briefs, Defendants raise three new legal defenses that were not raised before or during trial. Defendants have even relied on two documents not admitted into evidence or even identified by any witness at trial. Defendants' new legal defenses and documents from outside the trial record should be stricken. *See Pharmacyclics LLC v. Cipla Ltd.*, No. 18-192-CFC-CJB, 2020 WL 6581643, at *1-2 (D. Del. Nov. 10, 2020).

In *Pharmacyclics*, this Court found that Sandoz had waived its non-joinder-of-inventors theory where Sandoz first included its theory by burying it in an extremely long pre-trial order. *Id.* at *1-2. Defendants' actions here are even more egregious as their three new legal defenses were not in the pleadings, Pre-Trial Order, nor raised at trial. Defendants' failure to properly disclose their newly raised

legal defenses before the trial concluded deprived Plaintiffs of any opportunity to conduct discovery, shape its litigation strategy, secure expert testimony, or create a trial record to fully respond to Defendants' arguments. Accordingly, as in *Pharmacyclics*, the Court should strike the two documents discussed below and their three post-trial legal defenses. 2020 WL 6581643, at *1-2; *see also* Fed. R. Civ. P. 16(e); D. Del. LR 16.3 (stating that the pre-trial order can only be modified upon a showing of "manifest injustice"); *see also Wilson v. Muckala*, 303 F.3d 1207, 1215 (10th Cir. 2002) ("[C]laims, issues, defenses, or theories of damages not included in the pretrial order are waived even if they appeared in the complaint."); *Alza Corp. v. Andrx Pharm., LLC*, 607 F. Supp. 2d 614, 622 (D. Del. 2009) (striking defense from post-trial brief "[b]ecause Defendants have the burden of proof on a written description defense, the Court concludes that Defendants were obligated to raise this defense in their pre-trial briefing."); *Allergan, Inc. v. Barr Labs., Inc.*, 808 F. Supp. 2d 715, 735 (D. Del. 2011) (finding defendants waived an invalidity theory first raised post-trial).

A. This Court Should Strike Defendants' Newly Raised Defenses

1. The Court Should Strike Defendants' Newly Raised Inherency Defense

Defendants' Post-trial brief argues that Tapolsky-2005 "inherent[ly]" possess the pharmacokinetic elements of claims 4 and 5 of the '866 patent. (D.Br. 38.) This legal defense was not advanced before trial. Although Defendants argued that the

data for albuterol sulfate in dogs described in Tapolsky-2005 allegedly showed that pharmacokinetic elements of claims 4 and 5 were obvious, they did *not* argue that Tapolsky-2005 inherently possessed these claim elements. (*See* D.I. 229 (Pre-trial Order), Ex. 3A at 97-10.) Inherency is a legal defense separate and distinct from obviousness. Accordingly, this new defense should be stricken.

2. The Court Should Strike Defendants' Newly Raised Anticipation Defense

Defendants argue in their Post-trial brief that Vasisht-I anticipates claim 9 of the '539 patent. (DBr. 43-46.) This legal defense was also not raised in the Pre-Trial Order or during trial; Defendants only asserted that the claim was obvious. D.I. 229 (Pre-trial Order), Ex. 3A at 180, 190-201.) Defendants admit that they failed to raise the anticipation defense at trial in a footnote in their Post-trial brief. Defendants argued that although they only raised obviousness during trial, because anticipation "is the epitome of obviousness," they can raise the new anticipation defense post-trial. (DBr. 45 n.21.) This is not correct, and the case Defendants cite, *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019), is not applicable. In *Realtime*, the issue was the findings required to be made by the PTO Board. *Id.* The Federal Circuit held that even though the Board identified the rejection as section 103 (obviousness), it did not need to examine a motivation to combine because all the elements were disclosed in a single reference. *Id.* This case does not excuse

Defendants' failure to provide the requisite notice of their anticipation defense, which should also be stricken.

3. The Court Should Strike Defendants' Inequitable Conduct Defense

In their Post-trial brief, Defendants wrongly assert that “BDSI repeatedly made materially false statements and presented materially false data to the PTO in order to obtain the three patents-in-suit,” and that “BDSI manifestly intended the PTO to issue the patents-in-suit based on false pretenses.” (*See* DBr. 51.) Defendants go as far as to state that one of the inventors “falsified” data. (*Id.* at 46.) These types of allegations are inequitable conduct charges that are subject to the Federal Circuit’s high bar for alleging and proving both intent and materiality. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). But Defendants never pled inequitable conduct,¹ never raised it in their contentions pre-trial, and never mentioned it in their hundreds of pages of the Pre-trial Order. There was no mention of an alleged scheme by Plaintiffs to deliberately submit “materially” false data to the PTO in any pre-trial document and no mention of inequitable conduct.

Indeed, during trial, the Court asked whether Defendants were arguing “inequitable conduct or something like that.” (Tr. 188:10-14.) Plaintiffs’ counsel

¹ Inequitable conduct must be “pled with particularity” under Fed. R. Civ. P. 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009).

answered clearly: “*They are not.*” (Tr. 188:15 (emphasis added).) And the Court stated: “*That’s why I frankly didn’t pay that much attention to it.*” (Tr. 188:16-17 (emphasis added).)

Accordingly, there is no basis for any of Defendants’ allegations concerning alleged “material misrepresentations,” “falsification” of data, and inequitable conduct. These allegations are (1) that BDSI intended to deceive the PTO about a “Tapolsky” reference (DBr. 4, 33, 51, Defendants’ Proposed Findings No. 19, 141),² (2) that Dr. Vasisht filed a declaration during the prosecution of the ’539 patent that either “falsified” data or omitted material information (DBr. 46, 51),³ (3) that Dr. Finn misrepresented the pH of Suboxone and whether or not it was buffered in a declaration filed during the prosecution of the ’866 patent (DBr. 4, 33-34, 51),⁴ and (4) that Dr. Finn misrepresented the pH values for the BEMA 1 and BEMA 2 devices in the same declaration (DBr. 35-36, 51).⁵ Each of these allegations should be stricken from Defendants’ post-trial briefs and proposed findings.

B. This Court Should Strike Defendants’ Reliance on Two Documents not Admitted into Evidence

At page 27 of their Post-trial brief, Defendants quote from a so-called “publicly available” document that they *concede* was not admitted into evidence or

² Plaintiffs respond to the substance of this allegation at PBr. 27.

³ Plaintiffs respond to the substance of this allegation at PBr. 74-75.

⁴ Plaintiffs respond to the substance of this allegation at PBr. 59-63.

⁵ Plaintiffs respond to the substance of this allegation at PBr. 63-65.

even discussed by any witness, as would be necessary to lay a proper foundation for admission. (*See* Defendants Finding of Fact ¶94, n.3.) Moreover, the Court instructed the parties that exhibits had to be discussed at trial in order to be entered into evidence. (Tr. 544:13-16.) Accordingly, the unverified document and the assertions Defendants contend it supports should be stricken from Defendants’ brief and findings.⁶

Defendants cite another document in their reply brief at page 4, U.S. Patent No. 6,159,498, that was also not admitted into evidence. In its opening brief, Plaintiffs pointed out that the Tapolsky-2005 document Defendants are relying on in support of their inequitable conduct arguments is different from the document cited by BDSI during prosecution, which was the ’498 patent. (*See* PBr. 27.) As set forth in Plaintiffs’ Post-trial brief, and as discussed above, Defendants’ inequitable conduct argument was never raised by Defendants before the trial. In

⁶ This document appeared on Defendants’ trial exhibit list as DTX-364, but Defendants made a tactical decision not to admit it into evidence as Plaintiffs had objected to it. Then on May 26, 2021, the day all the briefs were due to be filed, Defendants removed all references from their papers to DTX-364, and instead just referred to it as a “publicly available” document. But judicial notice is a legal argument for admissibility of evidence at trial – *not after trial*. Furthermore, judicial notice does not allow a party to list a document on its trial exhibit list, intentionally decide not to try to move the document into evidence or even discuss it at trial, and then rely on the exhibit in its post-trial papers. *See Tamari v. Bache & Co. (Lebanon) S.A.L.*, 838 F.2d 904, 907 (7th Cir. 1988) (refusing to take judicial notice of a document where the “exhibit was available to the Tamaris at the time of trial, but they decided for their own reasons not to place it in evidence.”)

their reply Defendants are now relying on the '498 patent to support additional inequitable conduct arguments concerning "pentazocine," which Defendants *admit* were not raised during trial. (D. Reply Br. at 4 n.2.) Plaintiffs thus had no opportunity to address such arguments at trial. Accordingly, and as also set forth above, Defendants' arguments concerning inequitable conduct, and in particular, their arguments about the '498 patent in connection with pentazocine should be stricken as well.

III. CONCLUSION

BDSI respectfully requests that the Court strike the purported legal defenses of inherency, anticipation, and inequitable conduct that appear at pages 4, 33-36, 38-39, 40-41, 45 & n.21, 46, 51-52, of Defendants' Post-trial opening brief, and at pages 2, 4, 8, 10, 13-15, 22-23 of Defendants Reply brief, and proposed findings numbers 19, 94 & n.3, and 141, and also strike Defendants' reliance on documents that were not admitted into evidence or discussed at trial as set forth above.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com
Attorneys for Plaintiffs

OF COUNSEL:

Jennifer S. Swan
DECHERT LLP
3000 El Camino Real
Five Palo Alto Square
Suite 650
Palo Alto, CA 94306-2112
(650) 813-4800

Howard W. Levine
DECHERT LLP
1900 K Street, NW
Washington D.C. 20006-1110
(202) 261-3300

Justin J. Hasford
Daniel G. Chung
Michael R. Galgano
Bonnie Fletcher-Price
Daniele San Román
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

May 26, 2021

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on May 26, 2021, upon the following individuals in the manner indicated:

Dominick T. Gattuso, Esquire
HEYMAN ENERIO GATTUSO & HIRZEL LLP
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
Attorneys for Alvogen Defendants

VIA ELECTRONIC MAIL

Steven H. Sklar, Esquire
Gregory C. Bays, Esquire
Ashlee B. Szelag, Esquire
Wallace H. Feng, Esquire
David R. Van Buskirk, Esquire
James W. Sanner, Esquire
David M. Airan, Esquire
Jeremy Lowe, Esquire
LEYDIG, VOIT & MAYER
Two Prudential Plaza
180 North Stetson Avenue, Suite 4900
Chicago, IL 60601-6745
Attorneys for Alvogen Defendants

VIA ELECTRONIC MAIL

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)